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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,232	01/02/2004	Samuel Achilefu	MRD / 57CP	2153
26875	7590	04/20/2006	EXAMINER	
WOOD, HERRON & EVANS, LLP			JONES, DAMERON LEVEST	
2700 CAREW TOWER				
441 VINE STREET			ART UNIT	PAPER NUMBER
CINCINNATI, OH 45202			1618	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/751,232

Applicant(s)

ACHILEFU ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 2/10/06; 6/16/05; 5/25/04; 7/22/04; & 5/7/04
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 11-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-10 and 14-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/16/05; 5/25/04; + 7/22/04; + 5/7/04
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

#### **APPLICANT'S INVENTION**

1. Applicant's invention is directed to compositions and uses thereof as set forth in independent claims 1-4 and 11-14.

**Note:** Claims 1-31 are pending.

#### **RESPONSE TO APPLICANT'S ELECTION**

2. Applicant's election of Group XX filed 2/10/06 is acknowledged. In addition, Applicant's election of the species wherein W4 and X4 are sulfur; R25, R27, R28, R29, R31, R32, R33, and R35 are hydrogen; R24, R26, R34, and R36 are SO<sub>3</sub>T; R30 is glucose; Y4 and Z4 is (CH<sub>2</sub>)<sub>3</sub>SO<sub>3</sub>T; a4 is 1; b4 is 2; V is single bond; and T is a negative charge. The election is viewed as one without traverse since Applicant did not point out the supposed errors in the restriction requirement. Hence, the restriction requirement is still deemed proper and is therefore made FINAL.

Initially, Applicant's elected species was searched. However, since no prior art was found to reject Applicant's claims, the search was extended over the full scope of Group XX. In addition, it should be noted that the restriction was modified to such that claims 4-10 and 14-31 make up Group XX. Hence, Applicant is respectfully requested to cancel all subject matter not directed to the elected invention.

#### **WITHDRAWN CLAIMS**

3. Claims 1-3 and 11-13 were withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

#### **112 REJECTIONS (First Paragraph)**

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 4-10 and 14-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for glucose and for polyamino carboxylic acid, does not reasonably provide enablement for glucose derivatives of R groups and derivatives of polyamino carboxylic acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation wherein any glucose derivatives of R groups and derivatives of polyamino carboxylic acid are utilized.

The disclosure of the present invention is drawn to compounds, compositions and uses thereof as set forth in independent claims 4 and 14 having formula 4. While a skilled artisan would be motivated to select a glucose or polyamino carboxylic acid as substituents, the artisan would not know what glucose derivatives of R groups and derivatives of polyamino carboxylic acid Applicant is referring to which would be compatible with the instant invention. Hence, a skilled artisan in the art would not be able to readily ascertain the unlimited number of compound derived or obtained from glucose and polyamino carboxylic acids and containing essential elements of the parent substance. Thus, the skilled artisan would be forced to randomly test various glucose derivatives of R groups and polyamino carboxylic acid derivatives in order to determine which derivatives possess chemical properties which would yield similar results as that obtained when using glucose or polyamino carboxylic acid. Furthermore, the amount of guidance present in the specification fails to present the necessary instruction to determine what derivatives are encompassed by the claims.

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The specification does not provide guidance as to any specific substances which have the ability to behave as glucose derivatives of R groups or polyamino carboxylic acid derivatives nor does the specification disclose specific characteristics for such substances. In addition, the specification fails to provide guidance as to how any glucose derivatives of the R groups and polyamino carboxylic acid derivatives should be modified to generate the desired derivatives having properties compatible with the instant invention. No working examples are provided to provide such missing information. Without such information, one skilled in the art could not predict which substances out of the vast number of known substances and hypothetical substances are encompassed by Applicant's phrase "derivative" phrases. Therefore, due to the lack of guidance and the amount of experimentation required to identify any compounds that are glucose derivatives of R groups and polyamino carboxylic acid derivatives, substituents other than glucose and polyamino carboxylic acid are not properly enabled by the instant specification.

**112 REJECTIONS (Second Paragraph)**

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 4-10 and 14-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrases "glucose derivatives of R groups" and "polyamino carboxylic acid or its derivative thereof" are indefinite because one of ordinary skill in the art would not be able to readily ascertain the vast number of compounds derived or obtained from glucose or polyamino carboxylic acid and containing essential element of the parent substance.

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Claims 4-10 and 14-31: The claims as written are ambiguous because Applicant has not defined the variable R in the phrase 'glucose derivatives of R groups' (see independent claim 4, line 11, and claim 14, line 10).


**COMMENTS/NOTES**

8. The claims of Group XX are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious compositions and uses thereof as set forth in independent claims 4 and 14.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones  
Primary Examiner  
Art Unit 1618

April 17, 2006